

REMARKS

Claims 1 and 2 are pending in the application. Favorable reconsideration of the application is respectfully requested.

I. REJECTION OF CLAIMS 1 AND 2 UNDER 35 U.S.C. § 103(a)

Claims 1 and 2 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kitamura et al. (U.S. Publication No. 2004/0009218) in view of Weissmuller et al. (U.S. Patent No. 6,677,142). The Examiner states that Kitamura et al. discloses a linear amylose with a Mw of not less than 100 kDa and a narrow molecular weight distribution through enzyme synthesis by phosphorylase, wherein the biodegradability of the article formed thereof is excellent. The Examiner further states that Weissmuller et al. discloses an alpha-1,4-glucan chain containing polyssacharides for use as tablet fillers. The Examiner contends that it would have been obvious to those skilled in the art to use amylose as a disintegrant in a tablet in order to achieve the effects described in Kitamura et al., wherein biodegradability is equivalent to disintegration.

Applicants respectfully traverse the rejection for at least the following reasons. Neither Kitamura et al. nor Weissmuller et al. teach or suggest that the claimed alpha-1, 4-glucan possesses properties necessary for utility as a disintegrant in a tablet. As previously noted, a disintegrant has a unique function, defined as "*a substance used in tablet formulations to cause the tablet to break up on contact with moisture and exert its medical action promptly*" (see page 218 of "Merriam-Webster's Medical Desk Dictionary", attached as Exhibit A). The term "disintegrator" is considered to have the same meaning as "disintegrant" in the field of tablet manufacture. Thus, those skilled in the art would recognize that a disintegrant is specifically added to a tablet containing an active ingredient for the purpose of disintegrating the active ingredient after oral administration. The process of disintegration is well recognized as a physical phenomenon requiring the disintegration agent to be contacted with water and swollen thereafter resulting in the molded tablet to be physically disintegrated.

In contrast, Kitamura et al. merely discloses the use of amylose in order to exert the effects of excellent biodegradability of a pharmaceutical and does not disclose its use in a capsule. According to "Hawley's Condensed Chemical Dictionary Eleventh Ed. 1987", "biodegradability" is defined as *"the susceptibility of a substance to decompose by microorganisms, specifically the rate at which detergents and pesticides and other compounds may be chemically broken down by bacteria and/or natural environmental factors"* (see attached Exhibit B). Thus, the process of biodegradation is well recognized as a biological phenomenon requiring microorganisms or environmental factors to degrade the agent. Additionally, the production processes for preparing a capsule and tablet require differing starting material and forms, wherein i) a capsule is prepared by drying the membrane of a hydrolyzed macromolecule; and ii) a tablet is prepared by molding a solid powder. Because the teachings of Kitamura et al. correspond to an alternate administration form, the teachings of Kitamura et al. are not relevant to the presently claimed invention.

Furthermore, Weismuller et al. merely describes the use of a large amount of α -1,4-glucans having a degree of polymerization of not less than 1230 and not more than 37000, wherein these α -1,4-glucans having high molecular weight act as a diluent for bulk effect, wherein "filler" is considered to have the same meaning as "diluent" in the field of tablet manufacture and is not functionally active thereof. Specifically, page 214 of "Merriam-Webster's Medical Desk Dictionary" (Exhibit A attached) defines "diluent" is "a diluting agent (as the vehicle in a medicinal preparation)". Thus the diluent is used for the purpose of bulk effect. In contrast, the α -1,4-glucans used in the presently claimed invention have a degree of polymerization of not less than 186 and less than 1230 and a very narrow distribution of molecular weight, wherein the lack of high molecular weight, would result in them not exerting a bulking effect and use as a "filler". The respective functions associated with the terms "disintegrant", "biodegradability" and "filler" are clearly distinct from one another, and thus it would be well recognized by those skilled in the art that the properties necessary for a substance to achieve each of the above effects and use would also be distinct thereof.

Through innovative study the present inventors discovered a novel and unexpected property of the claimed α -1,4-glucan in the ability to disintegrate the active ingredient in a tablet, and thus discovered a novel and inventive use as a disintegrant thereof. A property that is inherent in the prior art, if not known at the time of the invention, cannot form a proper basis for rejecting a claimed invention as obvious under §103. Obviousness cannot be predicated on what is unknown. See *In re Shetty*, 195 U.S.P.Q. 753, 756-57 (CCPA 1977).

The problem solved by the present invention is directed to the development of a disintegrant for use in a tablet for improved disintegration of the active ingredient therein. None of (i) the problem to be solved, (ii) the mechanism to arrive at the solution, or (iii) the effects obtained therefrom are common between the presently claimed invention and the prior art. As a consequence, it appears that the Examiner has based the outstanding rejection upon ex post facto analysis and mere inference and supposition that those skilled in the art would have expected to have succeeded in achieving the claimed invention.

Because one skilled in the art would have had no reasonable expectation of success, based on the combined teachings of Kitamura and Weismuller that an α -1,4-glucan having a degree of polymerization of not less than 186 and less than 1230 and a dispersity of not more than 1.25 would be a disintegrator in a tablet, prima facie obviousness has not been established. Accordingly, the rejection under 35 U.S.C. §103(a) should be withdrawn.

II. PROVISIONAL DOUBLE PATENTING REJECTION

Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6-12, 18 and 21 of copending Application No. 10/333,267 (Kitamura et al., U.S. Publication No. 2004/0009218) in view of Weissmuller et al. (U.S. 6,677,142). The Examiner contends that claims 1 and 2 of the present application are prima facie obvious over claims 1, 2, 4, 6-12, 18 and 21 of Kitamura et al. in view of Weismuller et al.

Applicants respectfully traverse the rejection. As discussed above, neither Kitamura nor Weismuller disclose or suggest that an α -1,4-glucan having a degree of polymerization of not less than 186 and less than 1230, and a polydispersity of not more than 1.25 has a superior property as a disintegrant for tablets. Because one skilled in the art would have had no reasonable expectation of success, based on the combined teachings of Kitamura and Weismuller that an α -1,4-glucan having a degree of polymerization of not less than 186 and less than 1230 and a dispersity of not more than 1.25 would be a disintegrator in a tablet, prima facie obviousness has not been established. Therefore, the provisional double patenting rejection should be withdrawn.

III. CONCLUSION

Accordingly, claims 1 and 2 are believed to be allowable and the application is believed to be in condition for allowance. A prompt action to such end is earnestly solicited.

Should the Examiner feel that a telephone interview would be helpful to facilitate favorable prosecution of the above-identified application, the Examiner is invited to contact the undersigned at the telephone number provided below.

Should a petition for an extension of time be necessary for the timely reply to the outstanding Office Action (or if such a petition has been made and an additional extension is necessary), petition is hereby made and the Commissioner is authorized to charge any fees (including additional claim fees) to Deposit Account No. 18-0988.

Respectfully submitted,

RENNER, OTTO, BOISSELLE & SKLAR, LLP

/Heidi A. Boehlefeld/

Heidi A. Boehlefeld, Reg. No. 34,296

1621 Euclid Avenue
Nineteenth Floor
Cleveland, Ohio 44115-2191
Telephone (216) 621-1113
Facsimile (216) 621-6165



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218 disintegrate • displacement

dis-in-te-grate \dis-'int-ə-'grāt v b -grāt-ēg; -grāt-ēg w: to break or decompose into constituent elements, parts, or small particles ~ w: 1: to break or separate into constituent elements or parts 2: to undergo a change in composition (an atomic nucleus that ~s because of radioactivity) — **dis-in-te-gra-tion** \dis-'int-ə-'grā-shən n

disintegration constant n: **DISCAY CONSTANT**
dis-in-te-gra-tion \dis-'int-ə-'grā-shən n: one that causes the disintegration of something; **specif**: a substance used in tablet formulations to cause the tablet to break up on contact with moisture and exert its medicinal action promptly

dis-in-ter \dis-'n-'tər v: to take out of the grave or tomb — **dis-in-ter-ment** \dis-'n-'tə-mənt n

dis-in-tox-icate \dis-'in-'tō-'kāt v -cat-ēd; -cat-ēg
DETOXIFY 2 — **dis-in-tox-ica-tion** \dis-'in-'tō-'kā-shən n

dis-junc-tion \dis-'jŋk-'shən n: the separation of chromosomes or chromatids during anaphase of mitosis or meiosis
disk or **disc** \dis-'k: n: any of various rounded or flattened anatomical structures: as: a mammalian blood cell b: **BLIND SPOT** c: **INTERVERTEBRAL DISK** — see **SLEPPED DISK**

disk-ec-to-my also **dis-ec-to-my** \dis-'kēk-'tə-mē n, pl -mies: surgical removal of an intervertebral disk

disk-o-gram also **dis-o-gram** \dis-'kō-'gram n: a radiograph of an intervertebral disk made after injection of a radiopaque substance

dis-kog-ra-phy also **dis-co-gra-phy** \dis-'kō-'grā-fē n, pl -phies: the process of making a diskogram

dis-lo-cate \dis-'lō-'kāt, -lā: \dis-'lō-'kāt v -cat-ēd; -cat-ēg: to put (a body part) out of order by displacing a bone from its normal connections with another bone (he **dis-lo-cat-ed** his shoulder) also: to displace (a bone) from normal connections with another bone (the humerus was **dislocated** in the fall)

dis-lo-ca-tion \dis-'lō-'kā-shən, -lā: n: displacement of one or more bones at a joint: **LUXATION**

dis-mem-ber \dis-'mem-'bər v \dis-'mem-'ber-ēd; **dis-mem-ber-ing** \dis-'mē-'briŋ: to cut off or disjoin the limbs, members, or parts of — **dis-mem-ber-ment** \dis-'mē-'bər-mənt n

dismutase — see **SUPEROXIDE DISMUTASE**

dis-mu-ta-tion \dis-'myō-'tā-shən n: a process of simultaneous oxidation and reduction — used esp. of compounds taking part in biological processes

dis-so-dium \dis-'sōd-ē-'əm adf: containing two atoms of sodium in a molecule

disodium chromoglycate n: **CHROMOLYN SODIUM**

disodium ed-e-tate \ed-'ē-'tāt n: a hydrated disodium salt $C_{10}H_{14}N_2Na_2O_7 \cdot 2H_2O$ of EDTA that has an affinity for calcium and is used to treat hypercalcemia and pathological calcification

dis-so-mic \dis-'sō-'mīk adf: having one or more chromosomes present in twice the normal number but not having the entire genome doubled — **dis-so-my** \dis-'sō-'mē n, pl -mies

dis-so-mus \dis-'sō-'mŋs n, pl **dis-so-mi** \dis-'sō-'mī or **dis-so-mus-ē**: a 2-bodied tetraploid or hexaploid

dis-so-pyr-a-mide \dis-'sō-'pī-(ə-'mīd) n: a cardiac depressant $C_{12}H_{19}N_5O_7$ administered in the form of an association complex with phosphoric acid and used in the treatment of life-threatening ventricular arrhythmias

dis-or-der \dis-'ōrd-ər, ('dis-'ōrd v **dis-or-der-ēd**; **dis-or-der-ing** \dis-'ōrd-'riŋ: to disturb the regular or normal functions of

disorder n: an abnormal physical or mental condition: **AILMENT** (an intestinal ~) (a nervous ~)

dis-or-der-ēd adf: 1: not functioning in a normal orderly healthy way (~ bodily functions) 2: mentally unbalanced (a ~ patient) (a ~ mind)

dis-or-ga-ni-zation or **Brit** **dis-or-ga-ni-zation** \dis-'ōrg-'nī-zā-shən n: psychopathological inconsistency in personality, mental functions, or overt behavior (psychotic ~) (psychomotor ~) — **dis-or-ga-ni-zē** or **Brit** **dis-or-ga-ni-zē** \dis-'ōrg-'nī-zē v -nīz-ēd or **Brit** -nīz-ēd; -nīz-ēg or **Brit** -nīz-ēg

dis-or-ient \dis-'ōr-ē-'ent, -ōr-ē v: to produce a state of

disorientation in: **DISORIENTATE** (the next day the patient was ~ed but not comatose — *Jour. Amer. Med. Assoc.*)

dis-or-ien-ta-tion \dis-'ōr-ē-'ən-'tā-shən, -ōr-, -ēn-ē n: a usu. transient state of confusion esp. as to time, place, or identity often as a result of disease or drugs — **dis-or-ien-ta-tion** \dis-'ōr-ē-'ən-'tā-shən, -ōr-, -ēn-ē v -tāt-ēd; -tāt-ēg

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Dictionary*

ELEVENTH EDITION

Revised by

N. Irving Sax
and
Richard J. Lewis, Sr.



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into its component neutrons and protons. Neutron or proton binding energy is that required to remove a neutron or a proton from a nucleus; electron binding energy is that required to remove an electron from an atom or molecule. See also mass defect, fission.

bioassay. See assay.

"Biobate,"¹¹⁷³ TM for an enzymatic preparation for use in bating in the leather industry.

"Biocheck,"¹¹⁰⁸ TM for a family of biocides, fungicides, and slimicides.

Use: Controlling and eliminating microbiological growth in pulp and paper mill water systems as well as for antibacterial papers.

biochemical oxygen demand. (BOD). A standardized means of estimating the degree of contamination of water supplies, especially those which receive contamination from sewage and industrial wastes. It is expressed as the quantity dissolved oxygen (in mg/L) required during stabilization of the decomposable organic matter by aerobic biochemical action. Determination of this quantity is accomplished by diluting suitable portions of the sample with water saturated with oxygen and measuring the dissolved oxygen in the mixture both immediately and after a period of incubation usually five days.

See also sewage sludge, biodegradability, dissolved oxygen (DO), and oxygen consumed (COD) as related terms.

biochemistry. Originally a subdivision of chemistry but now an independent science, biochemistry includes all aspects of chemistry that apply to living organisms. Thus, photochemistry is directly involved with photosynthesis and physical chemistry with osmosis—two phenomena that underlie all plant and animal life. Other important chemical mechanisms that apply directly to living organisms are catalysis, which takes place in biochemical systems by the agency of enzymes; nucleic acid and protein constitution and behavior, which is known to control the mechanism of genetics; colloid chemistry, which deals in part with the nature of cell walls, muscles, collagen, etc.; acid-base relations, involved in the pH of body fluids; and such nutritional components as amino acids, fats, carbohydrates, minerals, lipids and vitamins, all of which are essential to life. The chemical organization and reproductive behavior of microorganisms (bacteria and viruses) and a large part of agricultural chemistry are also included in biochemistry. Particularly active areas of biochemistry are nucleic acids, cell surfaces (membranes), enzymology, peptide hor-

mones, molecular biology, and recombinant DNA.

See also biotechnology.

biocide. General name for any substance that kills or inhibits the growth of microorganisms such as bacteria, molds, slimes, fungi, etc. Many of them are also toxic to humans. Biocidal chemicals include chlorinated hydrocarbons, organometallics, halogen-releasing compounds, metallic salts, organic sulfur compounds, quaternary ammonium compounds, and phenolics. See also antiseptic, disinfectant, fungicide, bactericide.

biocolloid. An aqueous colloidal suspension or dispersion produced by or within a living organism. Blood, milk, and egg yolk are examples.

biocomputer. A computer in which the silicon in the microchips has been replaced by a synthetic protein or polypeptide coated with a silver compound, the combination behaving as a metallic semiconductor. Such chips have been made experimentally, they have the potential of improving the storage capacity and operating efficiency of silicon chips substantially. The materials used in the experimental chips were polylysine on a glass substrate coated with an acrylate polymer and treated with silver nitrate.

bioconversion. Utilization of animal manures, garbage, and similar organic wastes for production of fuel gases by digestion, gasification, or liquefaction.

See also biogas, biomass.

biocytin. (epsilon-N-biotinyl-L-lysine).

$C_{16}H_{28}N_4O_6S$.

Properties: A naturally occurring complex of biotin isolated from yeast. Water-soluble crystals, mp 228.5°C. It is believed to be an intermediate in the utilization of biotin by animal organisms.

biodegradability. The susceptibility of a substance to decompose by microorganisms, specifically the rate at which detergents and pesticides and other compounds may be chemically broken down by bacteria and/or natural environmental factors. Branched chain alkylbenzene sulfonates (ABS) are much more resistant to such decomposition than are linear alkylbenzene sulfonates (LAS) in which the long straight alkyl chain is readily attacked by bacteria. If the branching is at the end of a long alkyl chain (isoalkyls), the molecules are about as biodegradable as the normal alkyls. The alcohol sulfate anionic detergents and most of the nonionic detergents are biodegradable. Among pesticides the organo-

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phosphorus types while highly toxic are more biodegradable than DDT and its derivatives. Tests on a number of compounds gave results as follows: Easily biodegraded: n-propanol, ethanol, benzoic acid, benzaldehyde, ethyl acetate. Less easily biodegraded: ethylene glycol, isopropanol, o-cresol, diethylene glycol, pyridine, triethanolamine. Resistant to biodegradation: aniline, methanol, monoethanolamine, methyl ethyl ketone, acetone. Additives that accelerate biodegradation of polyethylene, polystyrene and other plastics are available.

bioengineering. Application of the principles and methods of chemical engineering to biotechnology.

bioelectrochemistry. Application of the principles and techniques of electrochemistry to biological and medical problems. It includes such surface and interfacial phenomena as the electrical properties of membrane systems and processes, ion adsorption, enzymatic clotting, transmembrane pH and electrical gradients, protein phosphorylation, cells, and tissues.

bioethics. An interdisciplinary science for which research facilities were established in 1971 encompassing the ethical and social issues resulting from advances in medicine and the biosciences. Its scope includes a number of areas of importance to chemistry, e.g., reproductive and genetic phenomena, organ transplants, gerontology and antiaging techniques, biological warfare, contraception, etc. The Kennedy Institute at Georgetown University, Washington, D.C., is the chief center for information about this developing aspect of biomedical science.

bioflavonoid. A group of naturally occurring substances thought to maintain normal conditions in the walls of the small blood vessels. The bioflavonoids are widely distributed among plants, especially citrus fruits, black currants, and rose hips (hesperidin, rutin, quercetin). They have little or no medicinal value.

biogas. Methane generated from animal manure by bacterial anaerobic digestion. Small-scale units have been in use for some years, and the possibilities of utilizing the tremendous quantities of manure available in the US as an energy source have stimulated investigation of large-scale production. One installation utilizing a thermophilic fermentation technique at 55-60°C has been operating in Florida since 1979, and another in Colorado since 1981. This energy source is also being exploited in China and India.

See also biomass.

biogeochemistry. A branch of geochemistry dealing with the interactions between living organisms and their mineral environment. It includes among other studies that of the effect of plants on weathering of rocks, of the chemical transformations that produced petroleum and coal, of the concentration of specific elements in vegetation at some time in the geochemical cycle (iodine in sea plants, uranium in some forms of decaying organic matter), and of the organic constituents of fossils.

biogenesis. See life, origin.

biogenic sediment. Sediment consisting of mineral grains that were once parts of organisms.

bioinorganic chemistry. Study of the mechanisms involved in the behavior of metal-containing molecules in living organisms, e.g., biological transport of iron, the effect of copper on nucleic acid and nucleoproteins, molybdenum and manganese complexes, etc.

bioluminescence. See chemiluminescence.

biomass. Any organic source of energy or chemicals that is renewable. Its major components are: (1) trees (wood) and all other vegetation; (2) agricultural products and wastes (corn, fruit, garbage ensilage, etc.); (3) algae and other marine plants; (4) metabolic wastes (manure, sewage); and (5) cellulosic urban waste. Conversion of these is performed in several ways: (1) by combustion (heat); (2) by fermentation (alcohol); (3) by gasification (synthesis gas); and (4) by anaerobic digestion (methane).

In terms of energy, wood is by far the most important component of biomass. It has become a significant source of industrial heat, e.g., in paper mills and power plants, and intensive cultivation of trees for this purpose is under way. Wood is also a potential source of alcohols; ethyl alcohol is produced from wood on large scale in Brazil as a gasoline substitute. Agricultural wastes are fermented or gasified to synthesis gas, manures and municipal waste yield methane (biogas) on digestion. In 1981, biomass supplied 3.5% of US energy requirements and this is expected to increase substantially.

biomaterial. Any material suitable for use as a surgical implant within the body to replace or support joints or tissues. They include such metals as aluminum, stainless steels, titanium, various forms of carbon, and especially plastics (polycarbonate, polyurethane, nylon, silicones). They have been used successfully in many areas of the body from hip and knee replacements to mas-